PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1594 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US 03/30227	International filing date *(day/month/year)* 24.09.2003	Priority date *(day/month/year)* 02.10.2002
International Patent Classification (IPC) or both national classification and IPC G21F5/018		
Applicant MALLINCKRODT INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims [illegible] been amended and are the basis for this report and/or sheets containing re[illegible] (see Rule 70.16 and Section 607 of the Administrative Instructions under [illegible]

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22.04.2004	14.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Björklund, A Telephone No. +49 89 2399-7310

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US 03/30227

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-25 as originally filed

Claims, Numbers

1-16, 18-21, 24-28 filed with telefax on 19.11.2004

Drawings, Sheets

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☒ the claims, Nos.: 17, 22-23

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 19-21,24-28

   because:

   ☒ the said international application, or the said claims Nos. 19-21, 24-28 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-3,5-16,18
	No:	Claims	1,4
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-16, 18
Industrial applicability (IA)	Yes:	Claims	1-16, 18
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item I
Basis of the report

1.The deletion of the features "the base having a hollow center section", "the cap having a hollow center section" and "a closure structure to releasably attach the cap to the base" broadens the scope of claim 1 such that it goes beyond the disclosure in the international application as filed (Article 34(2)(b) PCT). The examination has therefore been carried out as if these features had **not** been deleted (Rule 70.2(c) PCT).

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

2. The subject-matter of claims 19-21 and 24-28 define methods for treatment of the human or animal body by surgery which will not be examined (Rule 67.1(iv) PCT). Claim 19 comprises the step of ejecting the radiopharmaceutical from the syringe. In the light of the description ([00103], first two lines) it is implicit that the radiopharmaceutical is injected into a patient.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3. Reference is made to the following documents:

D1: EP0739017
D2: US5519931
D3: US4401108
D4: EP0122106
D5: US5828073
D6: GB849655
D7: US4847505
D8: FR1518130

4. Document D1 discloses (the references in parenthesis applying to this document):

A pharmaceutical pig for transportation of a liquid pharmaceutical in a syringe (the container 75 is suitable for transporting syringes), the pig comprising:
an elongate base characterised by an inner and outer shell of the base completely enclosing a base shielding element, the base having a hollow center section (fig. 8, items 61, 76);
an elongate cap removably attached to the base, the cap characterised by an inner and outer shell of the cap completely enclosing a cap shielding element (fig. 8, items 62, 77), the cap having a hollow center section; and
a closure structure to releasably attach the cap to the base (fig. 8, items 69a, 70a), wherein a portion of the cap shielding element overlaps a portion of the base shielding element (fig. 8, items 76 and 77 are overlapping).

Claim 1 is therefore not novel (Article 33(2) PCT).

5. Dependent claims 2-16 and 18 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT), the reasons being as follows:

The features of claims 2-16 and 18 are trivial design options known in the art (see D1-D8 and their respective citations in the search report).

CLAIMS

1. A pharmaceutical pig for transportation of a liquid radiopharmaceutical in a syringe, the pig comprising:

an elongate base having an inner and outer shell to completely enclose a base shielding element, the base having a hollow center section;

an elongate cap removably attached to the base, the cap having an inner and outer shell to completely enclose a cap shielding element, the cap having a hollow center section; and

a closure structure to releasably attach the cap to the base.

2. The apparatus of claim 1, further including a removable inner liner sized to slip into the hollow center section of the base.

3. The apparatus of claim 1, further including a flexible sleeve, at least a portion of which is transparent, to slip on and off at least a portion of the base to removably secure a label to the base.

4. The apparatus of claim 1, wherein the base shielding element is formed from lead and is tapered near the needle end of the syringe to reduce the overall weight of the pig and the cap shielding element is also formed from lead and is of generally uniform thickness and wherein the

cap shielding element and the base shielding element overlap to reduce radiation leakage from the pig.

5. The apparatus of claim 1, wherein the base shielding element is formed from a metallic-filled polymer composite material and is tapered near the needle end of the syringe to reduce the overall weight of the pig and the cap shielding element also formed from a metallic-filled polymer composite material and is of generally uniform thickness and wherein the cap shielding element and the base shielding element overlap to reduce radiation leakage from the pig.

6. The apparatus of claim 1, wherein the inner and outer shell of the base are formed from stainless steel and are welded together to hermetically enclose the base shielding element to prevent contamination of the base shielding element and the inner and outer shell of the cap are also formed from stainless steel and are welded together to hermetically enclose the cap shielding element to prevent contamination of the cap shielding element.

7. The apparatus of claim 1, wherein the closure structure is an elastomeric ring compressed between the cap and base and a plurality of keyhole-shaped slots in the cap sized and aligned to receive a plurality of screws having t-shaped heads extending from the base to removeably lock the cap to the base when the cap and base are rotated in opposite directions to engage the t-shaped heads in the keyhole-shaped slots.

8. An assembly including a pharmaceutical pig sized and arranged to transport a syringe, the assembly comprising:

a syringe having a needle, a barrel, a pair of wing-shaped finger grips, and a plunger;

a pharmaceutical pig including;

an elongate base having an inner and outer shell to completely enclose a base shielding element, the base having a hollow center section sized to surround the needle and at least a portion of the barrel of the syringe;

an elongate cap removably attached to the base, the cap having an inner and outer shell to completely enclose a cap shielding element, the cap having a hollow center section sized to surround at least a portion of the plunger of the syringe; and

a closure structure to releasably attach the cap to the base.

9. The apparatus of claim 8, wherein the syringe is selected from the group consisting of conventional syringes and safety syringes.

10. The apparatus of claim 8, further including a removable inner liner sized to slip into the hollow center section of the base, the inner liner further sized and arranged to surround the needle and at least a portion of the barrel of the syringe.

11. The apparatus of claim 8, further including a flexible sleeve, at least a portion of which is transparent, to slip on and off at least a portion of the base to removably secure a label to the base.

12. The apparatus of claim 8, wherein the base shielding element is formed from lead and is tapered near the needle end of the syringe to reduce the overall weight of the pig and the cap shielding element is also formed from lead and is of generally uniform thickness and wherein the cap shielding element and the base shielding element overlap to reduce radiation leakage from the pig.

13. The apparatus of claim 8, wherein the base shielding element is formed from a metallic-filled polymer composite material and is tapered near the needle end of the syringe to reduce the overall weight of the pig and the cap shielding element also formed from a metallic-filled polymer composite material and is of generally uniform thickness and wherein the cap shielding element and the base shielding element overlap to reduce radiation leakage from the pig.

14. The apparatus of claim 8, wherein the inner and outer shell of the base are formed from stainless steel and are welded together to hermetically enclose the base shielding element to prevent contamination of the base shielding element and the inner and outer shell of the cap are also formed from stainless steel and are welded together to hermetically enclose the cap shielding element to prevent contamination of the cap shielding element.

15. The apparatus of claim 8, wherein the closure structure is an elastomeric ring compressed between the cap and base and a plurality of keyhole-shaped slots in the cap sized and aligned to receive a plurality of screws having t-shaped heads extending from the base to removeably lock the cap to the base when the cap and base are rotated in opposite directions to engage the t-shaped heads in the keyhole-shaped slots.

16. An assembly including a pharmaceutical pig sized and arranged to transport a safety syringe filled with a liquid radiopharmaceutical, the assembly comprising:

a safety syringe having a needle, a barrel, a pair of wing-shaped finger grips, and a plunger;

a pharmaceutical pig including;

an elongate base and a base shielding element, the base having a hollow center section sized to surround the needle and at least a portion of the barrel of the syringe;

an elongate cap removably attached to the base and a cap shielding element, the cap having a hollow center section sized to surround at least a portion of the plunger of the syringe; and

a closure structure to releasably attach the cap to the base.

17. The apparatus of claim 16, further including a removable inner liner sized to slip into the hollow center section of the base, the inner liner further sized and arranged to surround the needle and at least a portion of the barrel of the syringe.

18. A pharmaceutical pig for transportation of a syringe, the syringe having a needle, a barrel, a pair of wing-shaped finger grips, and a plunger, the pig comprising:

an elongate base having an inner and outer shell formed from stainless steel to completely enclose a base shielding element, the base having a hollow center section sized to surround the needle and at least a portion of the barrel of the syringe;

an elongate cap removably attached to the base, the cap having an inner and outer shell formed from stainless steel to completely enclose a cap shielding element, the cap having a hollow center section sized to surround at least a portion of the plunger of the syringe;

a closure structure to releasably attach the cap to the base;

the cap shielding element having a generally uniform thickness;

the base shielding element being tapered in thickness in the area surrounding the needle to reduce the weight of the pig; and

the base shielding element partially overlapping the cap shielding element when the elongate cap is attached to the elongate base to reduce radiation leakage from the pig.

19. A method for transporting a syringe in a pharmaceutical pig, the syringe having at least a needle, a barrel, a pair of wing-shaped finger grips, and a plunger, the method comprising:

placing a syringe containing a liquid radiopharmaceutical in a pharmaceutical pig having:

an elongate base having an inner and outer shell to completely enclose a base shielding element, the base having a hollow center section sized to surround the needle and at least a portion of the barrel of the syringe;

an elongate cap removably attached to the base, the cap having an inner and outer shell to completely enclose a cap shielding element, the cap having a hollow center section sized to surround at least a portion of the plunger of the syringe; and

a closure structure to releasably attach the cap to the base;

transporting the pharmaceutical pig containing the syringe to a medical facility; and

transporting the pharmaceutical pig and the used syringe back to the radiopharmacy for disposal of the used syringe.

20. The method of claim 19, wherein the syringe is selected from the group consisting of conventional syringes and safety syringes.

21. The method of claim 19, wherein the hollow center section of the base further includes an inner liner.

22. A method for transporting a safety syringe in a pharmaceutical pig, the safety syringe having at least a needle, a barrel, a pair of wing-shaped finger grips, and a plunger, the method comprising:

placing a safety syringe containing a radiopharmaceutical in a pharmaceutical pig having:

an elongate base and a base shielding element, the base having a hollow center section sized to surround the needle and at least a portion of the barrel of the safety syringe;

an elongate cap removably attached to the base and a cap shielding element, the cap having a hollow center section sized to surround at least a portion of the plunger of the safety syringe; and

a closure structure to releasably attach the cap to the base;

transporting the pharmaceutical pig containing the safety syringe to a medical facility;

transporting the pharmaceutical pig and the used safety syringe back to a radiopharmacy for disposal of the used safety syringe.

23. The method of claim 22, wherein the hollow center section of the base further includes an inner liner.

24. A method for transporting a safety syringe in a pharmaceutical pig, the syringe being capable of being converted into a self-contained biohazard container and having at least a needle, a barrel, a pair of wing-shaped finger grips, and a plunger, the method comprising:

placing a safety syringe containing a radiopharmaceutical in the pharmaceutical pig having:

an elongate base having an inner and outer shell formed from stainless steel to completely enclose a base shielding element, the base having a hollow center section sized to surround the needle and at least a portion of the barrel of the safety syringe;

an elongate cap removably attached to the base, the cap having an inner and outer shell formed from stainless steel to completely enclose a cap shielding element, the cap having a hollow center section sized to surround at least a portion of the plunger of the safety syringe;

a closure structure to releasably attach the cap to the base;

the elongate base having an enlarged neck portion defining an inner shelf sized to

receive and support the wing-shaped finger grips of the safety syringe, the finger grips being captured between the cap and the shelf when the cap and base are

connected to prevent excessive movement of the safety syringe in the pig during transport; and

transporting the pharmaceutical pig containing the safety syringe to a medical facility;

converting the safety syringe into a self-contained biohazard container; and

transporting the pharmaceutical pig and the self contained biohazard container back to a radiopharmacy for disposal of the self-contained biohazard container.

25. The method of claim 24, wherein the hollow center section of the base further includes an inner liner.